DEPARTMENT OF HEA[redacted] & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

#19

Re: GEMZAR®
Docket No.: 96E-0314

JUL 24 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,808,614, filed by Eli Lilly & Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for GEMZAR®, the human drug product claimed by the patent.

The total length of the regulatory review period for GEMZAR® is 3,293 days. Of this time, 2,824 days occurred during the testing phase and 469 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 12, 1987.

   The applicant claims June 18, 1987, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 12, 1987, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: February 2, 1995.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for GEMZAR ® (NDA 20-509) was initially submitted on February 2, 1995.

3. The date the application was approved: May 15, 1996.

   FDA has verified the applicant's claim that NDA 20-509 was approved on May 15, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Margaret Brumm
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